NATIONAL ASSOCIATION
OF BEVERAGE IMPORTERS, INC.
30 COURTHOUSE SQUARE • SUITE 300 • ROCKVILLE, MD 20850
TELEPHONE (240) 453-9998 • FAX (240) 453-9358



April 4, 2003

Food and Drug Administration
Dockets Management Branch
(HFA-305)
5630 Fisher Lane, Room 1061
Rockville, MD 20852

ATTN: Dockets Management Branch – Docket No. 02N-0276

Dear Sir/Madam:

These comments are being submitted on behalf of the members of the National Association of Beverage Importers, Inc. (NABI). NABI is a national trade association that represents the interests of importers of alcohol beverages (beer, wine and distilled spirits). NABI members are responsible for the importation of a major share of all alcohol beverages imported into the United States.

NABI members welcome this opportunity to provide comments to the Food and Drug Administration (FDA) on its proposed regulations implementing the provisions of the Bioterrorism Preparedness and Response Act of 2002, (hereafter referred to as "the Act") that deal with "Registration." We believe FDA has proposed regulations that are unnecessary for the proper performance of FDA's functions under the Act and that the proposed registration regulations are duplicative of registration regulations already in place and enforced by the Alcohol and Tobacco Tax and Trade Bureau (TTB), formerly the Bureau of Alcohol, Tobacco and Firearms (BATF). In our opinion, FDA has failed to consider alternate options that would minimize the regulatory burden on our industry and at the same time provide FDA with all information necessary for FDA to perform its functions under the Act.

In August of 2002, NABI was part of an alcohol beverage coalition formed to respond to FDA's request for comment by stakeholders on FDA proposed regulations for implementing the provisions of the Act. The coalition submitted comments to FDA on August 30, 2002 (see attached Exhibit No. 1). In that comment, the coalition argued that FDA should not propose regulations that would duplicate regulations already in place and administered by other federal

02N-0276 C98

ROBERT J. MAXWELL
PRESIDENT

WINE-SPIRITS-BEER
nabi-inc@msn.com

BERNADEEN P. EMAMALI
CORPORATE SECRETARY

agencies. We believed then and continue to believe that the TTB collects all of the information that would be necessary for FDA to carry out most of its responsibilities for registration under the Act, with the only exception being the registration of foreign facilities.

We urge FDA not to adopt any regulations that request information duplicative of information already collected by other federal agencies. In that regard, Sections 302 (c) and 314 clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of federal agency activities. The Congressional Record is evidence of such intent.

The Senate proposal authorized the Secretary to require the maintenance and retention of other records relating to food safety in consultation with other federal departments and agencies that regulate food safety. (148 Cong Rec H 2685) Since the Secretary has authority under Section 701(a) of the FFDCA to issue regulations for the efficient enforcement of the Act in combination with other provisions, the Senate proposal was not adopted. (148 Cong Rec H 2685)

The House of Representatives also advocated close coordination with other federal agencies, such as the U.S. Customs Service, in implementing the notice requirement with a goal of minimizing and eliminating unnecessary, multiple and redundant notifications (147 Cong Rec E 2388) and encouraging simplicity and cooperation with respect to the registration requirement, reducing paperwork and the reporting burden on facilities (147 Cong Rec E 2388). Therefore, Congress recognized that the Act called upon functions of other federal agency activities and intended to coordinate, rather than duplicate, such functions.

Understanding the need to immediately obtain information relating to foods imported or offered for import into the United States in reaction to a crisis, NABI urges the FDA to implement a coordinated strategy with other federal agencies that have established regulatory measures governing beverage alcohol. FDA's coordination with other federal agencies, such as TTB and Customs vis-à-vis their respective regulatory schemes governing beverage alcohol, will best utilize the procedures and processes already in place to most efficiently "develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply" – the stated purpose of Title III of the Act.

The Secretary is required to establish registration requirements for specified food facilities by regulation necessary for effective enforcement. Congress encouraged efficient operation of the registration requirements and grants the

Secretary the ability to exempt certain facilities from the requirement of registration (148 Cong Rec H 2685). While we have no argument with FDA's obtaining all necessary information from foreign facilities, NABI urges FDA to accept the information obtained under the current permit system for domestic beverage alcohol producers, importers and wholesalers/distributors, thereby exempting such domestic facilities from registration requirements. The current permit system is far more comprehensive and grants the government greater control than this Act.

Requiring a domestic producer, importer,or distributor of beverage alcohol to register with FDA under Section 305 would be a duplication of existing TTB licensing and/or permit requirements. Not only are domestic producers, importers or wholesalers/distributors required to obtain federal permits, such facilities are also licensed and regulated by each state. Any applicant for a permit or registration with TTB must go through an extensive background and financial investigations and review. Foreign producers can only import beverage alcohol through an entity that holds a Federal Basic Importer's Permit.

Further, the electronic filing directive set forth in Section 305(d) was born out of the initiative to help reduce the paperwork and reporting burden, calling for a one-time registration. (148 Cong Rec H 2685) The goal of the one-time registration for domestic entities is fully accomplished by the regulatory scheme imposed by the TTB. Additional registration requirements imposed on the beverage alcohol industry would be duplicative, inefficient and costly, not only to the regulators but also to the regulated community.

If, in the final analysis, it is determined that foreign facilities that manufacture, process, pack or hold food for consumption in the United States must register, then FDA should propose a registration system that would allow U.S. agents to register the foreign facility.

FDA considered eight (8) options in the NPRM. None of the options, however, contains an analysis of FDA's accepting another federal agency's existing permit system as a registration under the Bioterrorism Act. The cost of this option would be significantly less – for both government and industry - than the option being proposed by FDA. None of the options contemplated by FDA considers "low risk" or "known importers." FDA could lessen the burden on itself and on the regulated industries by considering an option that would be less burdensome on "low risk" importers. This would include importers that have been accepted into the U.S. Customs and Trade Partnership Against Terrorism (C-TPAT). C-TPAT members have been thoroughly screened by the U. S. Customs Service. They

and their supply chain have been carefully examined by the U.S. Customs Service and have spent large sums of money to safeguard the food supply chain. C-TPAT applicants were promised that, after becoming members, they would enjoy preferential treatment when entering cargo into the United States. The regulations now proposed by FDA eliminate most of the benefits of C-TPAT membership. If an importer is registered with U.S. Customs as a C-TPAT or a Free and Secure Trade (FAST) member, they should not also be subjected to a FDA registration system.

Nor should a member of the alcohol beverage industry that holds a valid permit issued by the TTB or that is registered with the TTB, be required to register with the FDA. Under current law administered by TTB, the Secretary of the Treasury must find that the applicant for a permit to produce, warehouse, import or wholesale an alcohol beverage has not: (1) within five years of the application date, been convicted of a felony under federal or state law; or (2) within three years prior to the application date, been convicted of a misdemeanor under any federal or state law relating to liquor, including the taxation thereof.

The law also requires the Secretary of the Treasury to determine (1) that the applicant, by reason of his/her business experience, financial standing, or trade connection, is likely to commence business (operations) within a reasonable period of time and will maintain such operations in conformity with federal law and (2) that the proposed operations will not violate the laws of the state(s) in which they are to be conducted. While brewers are not required to obtain a permit, they must register with the TTB. The permit/registration system administered by TTB is far more comprehensive than anything currently proposed by FDA. Any FDA registration of domestic/U.S. importer alcohol beverage facilities would be redundant and a waste of government resources in addition to being a burden on the regulated industry. Clearly, the TTB permit system could easily be integrated into the FDA registration system.

Domestic alcohol beverage industry members are heavily regulated by TTB and have already provided most pertinent information to the TTB. Therefore, we strongly urge FDA to accept the information collected under the TTB's permit/registration system as a registration under "the Act."

Alternatively, FDA should also consider an option that would exempt members of the U.S. Customs Service, C-TPAT and FAST programs from re-registering with the FDA.

We think it is important that we restate, directly to FDA, our objections to the proposed regulations. The following comments are substantially the same as were submitted to OMB on March 5, 2003.

1) Is the proposed collection of information necessary for the proper performance of FDA functions, including whether the information would have practical utility

As outlined in the above paragraphs, NABI Members feel the proposed regulations are redundant and an unnecessary burden on the regulated industry. FDA did not consider an option that would have incorporated the registration systems of other federal agencies or considered "low risk" importers as identified by C-TPAT and FAST.

FDA is proposing to require more information from the registrant beyond that mandated by the Bioterrorism Act. The volume of information alone brings its utility into question. FDA has not justified its need for the information, especially in light of the fact that in our view the collection of such information is redundant.

2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

We believe that FDA has grossly underestimated the number of respondents/registrants. It is impossible to tell from reading the NPRM just how FDA arrived at the number of 205,405 respondents (see Table 48.) Does that number include the thousands upon thousands of small vineyards that also produce a small quantity of wine, hoping that they will get a chance to sell it in the United States? Not registering would greatly reduce any chance that the small vineyard might have of getting a U.S. importer to handle their wine. In the NPRM, FDA estimates that 205,405 foreign facilities and 202,046 domestic facilities would be required to register with the Agency. NABI believes this estimate is low. It appears that, in the Preliminary Regulatory Impact Analysis, upon which the numbers of respondents are based, FDA fails to give appropriate weight or clarification to the number of very small facilities, including small local holding facilities and transportation facilities. Transportation vehicles will hold food while it is in transit and transportation vehicles do not appear to be exempt from the scope of the statute. Absent FDA's precise interpretation of the scope of the statute, NABI believes that the Agency has underestimated the number of respondents.

Hour Reporting Burden

The Agency's cost estimates are understated and based on assumptions that do not reflect typical operating practices. In the proposed rule, FDA estimates the time it would take for a respondent to read, understand, collect data and complete the registration form. Estimates range from two hours to twelve hours per facility, depending on whether the respondent has access to the Internet and whether the respondent is fluent in English. FDA provides no justification for this estimate other than to explain the variables introduced by differences in Internet access and English fluency.

To research and understand the rules, any company would need far more than the one hour FDA factored into the economic impact assessment. The proposal alone is 40 pages of fine print in the Federal Register. The FDA explanatory video takes another hour to watch. No time was allocated for the task of evaluating the implications of the proposed rules to current business systems or for preparing comments. When the final rules are published, assuring compliance will involve reading and understanding the final Federal Register document, as well as any accompanying question and answer documents or videos. The "FDA product code" scheme is not used by the alcohol beverage industry, so companies first would need to learn the FDA system and then will need to classify products by facility.

The hour estimates of reporting burden are predicated on the bulk of the registration being done by administrative workers. NABI believes this estimate has failed to capture accurately the time needed to assemble the data on the facility. The data required is likely to be beyond the familiarity of most administrative workers in a facility. A supervisor will need to collect the registration information, which the administrative worker would then enter on the paper form used to complete the electronic registration. Some of the data fields require research and/or input from additional persons as well as validation checks.

FDA proposes to require management certification that the submission is accurate, but does not appear to have factored manager time into the economic analysis. No systems development costs were included and the entire form may take more than 15 minutes for a responsible party to review and certify. Furthermore, given the need for higher-level personnel involvement, the actual average wage rate for all company personnel involved in facility registration activities likely would exceed the $33 per hour weighted average wage rate estimate used by FDA.

U.S. Agents

Foreign facilities all must identify at least one U.S. agent. The registration form presupposes that a foreign facility will have one U.S. agent, when, in fact, it may have numerous U.S. agents, depending upon the nature and business practices of the foreign facility. NABI believes that FDA goes beyond the scope and intent of the act in presuming to require changes in business practices, which would unduly constrain domestic commerce and international trade.

In the case of alcohol beverages, it is common for a foreign supplier to have more than one authorized importer, often divided by designated state territories. In the NPRM, option two, FDA states that the foreign facility can have only one U.S. agent. This restriction would appear to be unreasonable.

FDA is, in fact, saying that a U.S. agent would be responsible for the actions of multiple importers. This appears to be an unreasonable burden on that one U.S. agent.

Reporting Frequency

FDA has estimated that 20 percent of facilities would have a material change regarding its registration information after one year. Put another way, FDA estimates that a facility is likely to have a material change in its registration information once every five years, on average. FDA does not draw a distinction in the proposed rule between "material" and "insignificant" changes to the registration information. Thus, as proposed, it appears that every change to the registration information must be reported to FDA within 30 days. Considering that some of this data involves personal information (name and title of personnel for emergency contact, addresses, telephone numbers, email addresses) subject to frequent change, or changes in product category information, it is unreasonable to estimate that a facility will change its information only once every five years. Personnel changes in emergency contacts, person completing the registration or authorized party could be more frequent, given promotions, separations, relocations or changes in assignment of personnel. Companies often add and change product categories or reorganize the corporation so that the trade name changes. These changes are fairly frequent. Several large alcohol beverage corporations have reorganized significantly within the last five years, with several changes to personnel, titles, locations and trade names. FDA's assumption represents a serious underestimation in the frequency of registration information changes. NABI believes a more realistic estimate is that 50 percent of facilities will have at least one change every year.

With respect to frequency of reporting, FDA estimates that any facility would likely change its registration information only once a year. FDA proposes to require that changes to registration information be executed within 30 days of a change, thus increasing the likelihood that a facility may have twelve annual opportunities to change registration information. Given the need for changing registration information is triggered by any change in data currently registered and some of the data elements are likely to change frequently, NABI believes one change per facility per year is not a realistic estimate. A realistic estimate would reflect several changes per year per registered facility.

The reporting burden can be reduced if FDA were to change its proposed requirements that changes be made in 30 days. The longer the period permitted for changes, the less burden on the registration system and the less reporting burden on respondents, with little or no degradation in timeliness of information.

3) How can the quality, utility and clarity of the material be enhanced

It can be enhanced by reducing the duplication caused by FDA's attempt to establish a "stand alone" registration system. FDA should rely on other agencies' permit/registration systems that have served the government's needs well for many years.

4) How can the burden of collecting information on respondents be reduced

As it relates to the alcohol beverage industry, most of the information required under the Bioterrorism Act is already on file with the TTB. In fact, BATF submitted a detailed memo to FDA describing its permit/registration scheme. A copy of the BATF memo is attached (See attached Exhibit No. 2) for your ready reference. It would appear, from reading the NPRM, that FDA completely ignored the alcohol beverage industry letter on this issue and the BATF memo.

NABI has many small members. These small companies will undoubtedly have to retain lawyers, consultants or customs brokers to help them comply with the proposed regulations. The costs for that professional assistance will certainly exceed the $58 to $83 estimate of FDA. The proposed rule will cause many small companies, both in the United States and in other parts of the world, to deal with complex government regulations. They will undoubtedly need a considerable amount of professional help.

## CONCLUSION

In summary, we ask that FDA coordinate with other federal agencies to insure duplication of information is avoided and the permit and registration systems of other federal agencies be incorporated into the Bioterrorism Act registration system. We see no reason, legal or otherwise, why FDA cannot deem the permit/registration systems of TTB to suffice as registration for the purposes of the Bioterrorism Act of 2002. Foreign producer information can be obtained by FDA to supplement the TTB permit system.

We thank you for this opportunity to comment on these proposed regulations. We ask that FDA rewrite its proposed regulations to ensure that the Bioterrorism Act regulations do not unnecessarily burden the private sector or negatively affect the economy. We stand ready to work with FDA in the drafting of regulations that meet the requirements of the act without placing an unnecessary burden on the regulated industry.

If we can be of further assistance, please do not hesitate to call on us.

Sincerely,

Robert J. Maxwell
President – NABI

Attachments (2)
8/30/02, Joint Industry Comment
BATF Letter to FDA